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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,938

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Yusuke Nakamura

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/518,938

Applicant(s)

NAKAMURA ET AL.

Examiner

Maria Leavitt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1-3, drawn to a method of diagnosing colorectal tumors in a subject by detecting expression level of one or more marker genes in a specimen collected from said subject.
- II. Claims 4, 6-9 drawn to a method for screening a therapeutic agents useful in treating or preventing colorectal tumors comprising contacting a candidate compound with a cell expressing one or more marker genes, a vector comprising the transcriptional regulatory region of one or more marker genes and/or a protein encoded by a marker gene.
- III. Claims 5, 8-9 drawn to a method for screening a therapeutic agents useful in treating or preventing colorectal tumors comprising administering a test compound to a test animal and measuring the expression level of one or more marker genes in a biological sample from said test animal.
- IV. Claims 10-19, drawn to a method for treating or preventing colorectal tumors.
- V. Claims 20-24 drawn to a method for diagnosing adenoma and/or carcinoma.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

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“If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present”

37 CFR 1.475 (d) also states:

“If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)”.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking Groups I-V appears to be that they all relate to methods diagnosing, treating and/ or preventing colorectal tumors in a subject by administering to a subject a molecule to reduce (e.g., marker genes of tables 1, 3 and 4) or enhance expression of gene markers selectively modulated in colorectal tumors. However, prior art has described expression profiles of 50 genes expressed differentially in adenomas and carcinomas (Lin et al., *Oncogene* (2002) 21, 4120-4128) for diagnosis of colorectal tumors. Additionally, each invention have different modes of operation, each being used in different capacities, have different functions and produce different effects. For example, a method for screening a therapeutic agents useful in treating or preventing colorectal tumors of Group II requires administration of the test compound to a subject which is not required by the method of diagnosing colorectal tumor of Group I. Therefore, the technical feature linking the invention of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

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This application contains claims directed to more than one species of the generic invention. Generic claims will be examined as they correspond to the selected groups. Currently claims 1 and 16 are generic, for example. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PTC Rule 13.1

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction.

Should Groups I be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species: marker genes from Table 1 and Table 2.

1) Applicant is required to choose one specifically named gene marker as recited in claim 1.

The species are independent or distinct because there are methods comprising marker genes unregulated or downregulated in colorectal tumors having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claim 1 is generic.

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Should Groups II be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species: marker genes from Table 1, Table 2, Table 3 and Table 4.

2) Applicant is required to choose one specifically named marker gene as recited in claims 4, 6, 7, 8 and 9.

The species are independent or distinct because there are methods comprising maker genes unregulated or downregulated in colorectal tumors having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 4, 6 and 7 are generic.

Should Groups III be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species: marker genes from Table 1, Table 2, Table 3 and Table 4.

3) Applicant is required to choose one specifically named marker gene as recited in claims 5, 8 and 9.

The species are independent or distinct because there are methods comprising maker genes unregulated or downregulated in colorectal tumors having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claim 5 is generic.

Should Groups IV be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species: marker genes from Table 1, Table 2, Table 3 and Table 4;

4) Applicant is required to choose one specifically named marker gene as recited in claims 10-19.

The species are independent or distinct because there are methods comprising maker genes unregulated or downregulated in colorectal tumors having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claim 10 is generic.

This application contains claims directed to the following patentably distinct species: Antisense nucleic acid and antibody or fragment against a maker gene or protein encoded by a marker gene.

5) Applicant is required to choose one specifically named marker gene as recited in claims 11 and 12.

The species are independent or distinct because there drawn to methods for treating or preventing colorectal tumors by using molecules comprising maker genes unregulated or

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downregulated in colorectal tumors having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claim 10 is generic.

Should Groups V be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species: marker genes from Table 1, Table 2, Table 3 and Table 4;

6) Applicant is required to choose one specifically named marker gene as recited in claims 20-23.

The species are independent or distinct because there are methods comprising marker genes unregulated or downregulated in colorectal tumors having different chemical structures, physical properties, and biological functions as a result of containing different expressed genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claim 21, 21 and 22 are generic.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the



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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

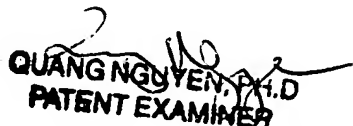
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776 or the examiner's supervisor, Nguyen Dave, can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

  
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